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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,030	02/11/2004	Samuel I. Stupp	8256	2190

22922 7590 05/06/2005

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EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/777,030

Applicant(s)

STUPP ET AL.

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Restriction to one of the following inventions is required under 35 U.S.C. §121:

- I. Claims 1-7, drawn to a nanotextured biocompatible composite
- II. Claims 8-13, drawn to a method of promoting growth of a calcium phosphate composition.
- III. Claims 14-20, drawn to a method of coupling peptide amphiphiles to a biocompatible substrate.

The claimed inventions are distinct.

Inventions I and II are not related as process of making and product made. They are related in that both require the presence of calcium phosphate and polylysine; apart from this, there is no connection between them, at least insofar as restriction is concerned. Nor are inventions I and II related as product and process of use. Nevertheless, in the event that Group I is elected and found allowable in its present form, and in the further event that agreement can be reached as to further limitations on the invention of Group II prior to rejoining, the possibility of rejoining Group II will be considered.

Similarly, inventions I and III are also not related as process of making and product made. Claim 14 is drawn to a method of coupling peptide amphiphiles to a biocompatible substrate, but imposes no limitations on the components that must be present in the final

product. However, in the event that claim 14 were instead drawn to a method of making the nanotextured biocompatible composite of claim 1, then the following form paragraph would apply:

The inventions in question are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)).

If claim 14 were amended in this way, and in the further event that Group I were found allowable, rejoining of Group III would at that point become appropriate.

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

. . . .

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect disclosed species (as follows) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the event that applicants choose Group I for initial examination, election of a fully defined "nanotextured biocompatible composite" composition is required, with 100% of the components fully accounted for. In the event that the composition contains nanofibers of peptide amphiphiles coupled to polylysine, what is the sequence or structure of at least one peptide amphiphile that is present?

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In the event that applicants choose Group II for initial examination, election of a specific "amine-modified phosphate composition" is required, i.e., the one that is participating in the "growth" process. Second, election is required of a specific composition that is to exhibit growth. Is it calcium phosphate? Is it a crystalline material, a non-crystalline polymer, is it cells or tissues?

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In the event that applicants choose Group III for initial examination, election of the following is required:

- a) at least one peptide amphiphile that is present;
- b) one of the following:
 - (i) a process which requires contacting the mineral phase with an acid;
 - (ii) a process which requires contacting the mineral phase with a degradative enzyme;
 - (iii) the elected process requires contacting the mineral phase with neither an acid nor a degradative enzyme
- c) election of one of the following is further required:
 - (i) the elected process requires culturing mammalian cells on peptide amphiphiles, or
 - (ii) the elected process does not require culturing mammalian cells on peptide amphiphiles

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Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

✦

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

D. Lukton

DAVID LUKTON
PATENT EXAMINER
GROUP 1800